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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,009	03/11/2004	Lee R. Dreyer	025803-00003	3896
4372	7590	06/21/2005	EXAMINER	
ARENT FOX PLLC 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036				FLOOD, MICHELE C
			ART UNIT	PAPER NUMBER
				1654

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/797,009	DREYER, LEE R.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
  - 4a) Of the above claim(s) 21-49 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. <u>6/9/2005</u> .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/29/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, Claims 1-20, in the reply filed on March 29, 2005 is acknowledged. Further acknowledgment is made of Applicant's species election containing the following herbal active ingredients: Aconitum Napellus, Arnica Montana, Bellis perennis, Bryonia alba, Calendula officinalis, Hamamelis virginiana, Hypericum perforatum, Ledum palustre and Ruta Graveolens. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The originally elected species was not found; therefore the requirement for species election has been withdrawn. The Claims were examined on the merits taking each of the species of the Markush Group in Claims 1 into consideration.

**Claims 1-20 are under examination.**

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The

disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant should avoid the use of phrases, such as, "One of the objects of the present invention is directed to" or "The present invention is also directed to" or "Within the scope of the invention".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in its entirety, as originally filed, is generally indefinite and confusing because the claim recites a composition comprising (a); (b); or (c), wherein each of (a), (b) and (c) recite preparations comprising claim-designated ingredients and claim-designated number of ingredients. As drafted, it is unclear as to the subject matter Applicant intends to direct the claimed invention because no conjunction appears to between the recitation of the subject matter of (a) and (b). Therefore, it is unclear as to whether the claimed invention is directed to a composition comprising (a) and (b) or (c); or whether the claimed invention is directed to a composition comprising (a) or (b) or (c). Therefore, the metes and bounds of the claimed subject matter is rendered vague and indefinite because it is uncertain as to the limitations for which Applicant intends to seek patent protection.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by King Bio Natural Medicines (U), as evidenced by Dr. Frank J. King (V) and Internet Archive Wayback Machine (W).

Applicant claims a formulation comprising herbal active ingredients, wherein the herbal active ingredients comprise:

(a) tinctures and/or homeopathic preparations of 8 or all of Bellis perennis,

Calendula officinalis, Hamamelis virginiana, Arnica Montana, Hypericum perforatum, Aconitum napellus, Ledum palustre, Bryonia alba and Ruta graveolens;

(b) tincture and/or homeopathic preparations of at least 5, 6 or 7 of Bellis perennis,

Calendula officinalis, Hamamelis virginiana, Arnica Montana, Hypericum perforatum, Aconitum napellus, Ledum palustre, and Ruta graveolens; or

(c) tinctures and/or homeopathic preparations of at least 5, 6 or 7 of *Bellis perennis*, *Calendula officinalis*, *Hamamelis virginiana*, *Arnica Montana*, *Hypericum perforatum*, *Aconitum napellus*, *Ledum palustre*, *Bryonia alba* and *Ruta graveolens*, with the proviso that the formulation does not contain tincture(s) and/or homeopathic preparation(s) of *Echinacea augustifolia* and *Symphytum officinale*.

Applicant further claims the formulation of claim 1, the herbal active ingredients comprising tinctures and/or homeopathic preparations of at least 5, 6 or 7 of *Bellis perennis*, *Calendula officinalis*, *Hamamelis virginiana*, *Arnica Montana*, *Hypericum perforatum*, *Aconitum napellus*, *Ledum palustre*, *Bryonia alba* and *Ruta graveolens*, with the proviso that the formulation does not contain tincture(s) and/or homeopathic preparation(s) of *Echinacea augustifolia* and *Symphytum officinale*.

King Bio Natural Medicines teaches a formulation, "911 Stress Control 2 oz Liquid", comprising homeopathic preparation of *Bryonia alba* and homeopathic preparations of *Bellis perennis*, *Calendula officinalis*, *Arnica Montana*, *Hypericum perforatum* and *Aconitum napellus*, wherein each ingredient is in equal volumes of 10X, 30X, and 100X potencies in a pure water base. As evidenced by the information provided by Internet Archive Wayback Machine, the provided webpage teaching the aforementioned product appeared on the world wide web as early as February 23, 2002.

In a telephonic interview, on June 9, 2005, Dr. Frank J. King (Founder and President of King Bio Natural Medicine, Inc.) stated that the aforementioned product was in public use and for sale in March 1990.

The reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10-14, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over King Bio Natural Medicines (U) in view of Diec et al. (A\*).

Applicant's claimed invention of Claims 1 and 10-13 was set forth above. Applicant further claims the formulation of claim 1 or claim 10 or claim 12, further comprising a gel base comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben.

The teachings of King Bio Natural Medicines were set forth above. The teachings of King Bio Natural Medicines teach the instantly claimed invention except for a gel base comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben. However, it would have been obvious to one of ordinary skill in the art to modify the formulation taught by King Bio Natural Medicines by adding the instantly claimed ingredients because at the time the invention was made

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Diec taught a gel comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben that was useful in the making of cosmetic or dermatological preparations. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to modify by adding the instantly claimed ingredients to the formulation taught by King Bio Natural Medicines in the making of a gel because Diec taught that the referenced gels had broad diversity of uses, including skin formulations, cosmetic and dermatological preparations, and medical/pharmaceutical formulations (See Column 4, lines 34-40.) and delivered in the form of an aerosol spray (See Column 27, lines 5-10).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

\* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**MICHELE FLOOD**  
**PRIMARY EXAMINER**

Michele Flood  
Examiner  
Art Unit 1654

MCF  
June 9, 2005